

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION

MDL No. 1456

Master File No. 01-12257-PBS

Subcategory No. 06-11337-PBS
Civil Action No. 08-cv-10852

THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-A-Care of
the Florida Keys, Inc., by and through its principal
officers and directors, Zachary T. Bentley and
T. Mark Jones v. Actavis Mid Atlantic LLC, et al.*

Judge Patti B. Saris

Magistrate Judge Marianne B. Bowler

**DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR
MOTION TO COMPEL THE STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION TO PRODUCE DOCUMENTS**

Defendants Actavis MidAtlantic LLC, Alparma USPD Inc. f/k/a Barre National Inc., and Barre Parent Corp. (collectively "Actavis MidAtlantic"); Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par"); Sandoz Inc. f/k/a Geneva Pharmaceuticals Inc. ("Sandoz"); and Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. f/k/a Schein Pharmaceutical, Inc. (collectively, "Watson") (together, the "Defendants") respectfully submit this memorandum in support of their motion to compel the State of Florida (the "State" or "Florida") Agency for Health Care Administration ("AHCA") to produce documents.

Defendants request relevant documents, and their requests are reasonable and not overbroad or unduly burdensome. Indeed, there is no real burden on AHCA to comply, as the agency likely would have to produce the same documents in a related lawsuit that is pending in Florida state court where Florida is a plaintiff and Sandoz and Actavis are defendants.

BACKGROUND

I. DEFENDANTS' EFFORTS TO OBTAIN DISCOVERY FROM AHCA

On June 28, 2010, Defendants served a subpoena (the "Subpoena") on AHCA requesting the production of documents.¹ The State objected to the Subpoena on July 12, 2010.² On behalf of Defendants, counsel for Sandoz contacted the State to discuss the Subpoena, and the State and Sandoz conferred by telephone on September 24, 2010.³ The State advised, *inter alia*, that it had previously produced documents in a pharmaceutical pricing lawsuit involving the drug manufacturer Mylan. Sandoz subsequently contacted counsel for Mylan to obtain the production. By October 26, 2010, counsel for Sandoz had received the entire Mylan production, which it began to review.

Over the next several months, Sandoz reviewed the Mylan production, which consisted of approximately 69,000 pages, as well as document productions of approximately 260,000 pages previously made in the multidistrict litigation by the Centers for Medicare and Medicaid Services ("CMS"). Counsel for Sandoz determined that it was not in possession of, among other things, four specific categories of documents: (1) Florida's Medicaid State Plans pertaining to pharmaceutical reimbursements; (2) proposed or actual amendments to those State Plans; (3) documents and communications concerning those State Plans; and (4) studies or analyses of pharmacy acquisition costs and dispensing fees. Sandoz wrote to the State on March 24, 2011

¹ See Exhibit ("Ex.") 1.

² July 12, 2010 Letter from Daniel Lake to Stefan Mentzer (Ex. 2).

³ The State advised that the earliest date its representatives would be available for a telephone conference was August 16, 2010. The State subsequently cancelled that conference and made itself next available the following month.

requesting production of these categories of documents, which significantly narrowed the requests set forth in the Subpoena.⁴

The State objected and counsel for Sandoz and the State discussed the requested production by telephone on April 5. In the course of discussions, the State informed Sandoz that it had developed an electronic database of documents kept by relevant current and former State employees.⁵ The State assembled this database in connection with the pending state action in which it is a plaintiff, *State of Florida ex rel. Ven-A-Care of the Florida Keys, Inc. v. AlphaPharma, Inc., et al.*, Civil Action Nos. 98-CA-3032F, 03-CA1165A.⁶ On April 6, Sandoz provided the State with a list of proposed search terms likely to identify documents responsive to Sandoz' narrowed requests,⁷ and on April 13 the State provided a spreadsheet indicating, for each custodian, the number of documents containing each search term. Exhibit 6 hereto includes a copy of the spreadsheet. On April 19, Sandoz proposed that the State produce the documents of a reduced number of custodians using the same search terms as proposed on April 6, which would result in a production of about 153,000 documents, significantly less than the approximately 719,000 documents contained in the entire database.⁸ Both of these numbers are

⁴ Mar. 24, 2011 Letter from Stefan Mentzer to Gretchen Wallace (Ex. 3).

⁵ Apr. 6, 2011 E-mail from Stefan Mentzer to Gretchen Wallace (Ex. 4, at 1).

⁶ *Id.*; see Second Amended Complaint (Ex. 5) (excluding exhibits).

⁷ Apr. 6, 2011 E-mail from Stefan Mentzer to Gretchen Wallace (Ex. 4, at 7).

⁸ Apr. 19, 2011 E-mail from Stefan Mentzer to Gretchen Wallace (Ex. 7, at 1); see Ex. 6, at 14 (column "Grand Total," showing 718,993). The State has asserted that the number of documents resulting from Defendants' proposed searches is 172,859 (not 153,000) but Defendants are unable to determine the basis for those calculations.

probably inflated, as a document that contains two search terms, such as “AWP” and “4.19B,” is counted twice.⁹

While awaiting the State’s response, Defendants served a second subpoena on AHCA on May 10, 2011 (the “2011 Subpoena” (Ex. 8)) to reflect the narrowed categories of documents Defendants were requesting.¹⁰ On May 13, 2011, the State refused Sandoz’ proposal, objected to the 2011 Subpoena, and requested that Defendants withdraw both subpoenas.¹¹

II. THE DOCUMENTS REQUESTED IN THIS MOTION

Defendants request an order compelling the State to produce two categories of documents:

1. The portions of Florida’s Medicaid State Plans that concern pharmaceutical reimbursements, in particular Section 4.19(b) and Attachment 4.19-B of each Florida Medicaid State Plan.¹²
2. Documents obtained from the files of select employees of AHCA’s Office of the Deputy Secretary for Medicaid, Bureau of Medicaid Pharmacy Services, and Bureau of Medicaid Program Analysis that contain certain targeted search terms.¹³

⁹ May 13, 2011 Letter from Gretchen Wallace to Stefan Mentzer (Ex. 9, at 2 ¶ 6).

¹⁰ The 2011 Subpoena did not request new documents, as its requests are encompassed by the requests made in the 2010 Subpoena.

¹¹ May 13, 2011 Letter from Gretchen Wallace to Stefan Mentzer (Ex. 9).

¹² This request is encompassed by Document Request 1 in the 2010 Subpoena (Ex. 1) and Document Request 1 in the 2011 Subpoena (Ex. 8).

¹³ The document custodians and search terms for which Defendants request production are set forth in Document Request 2 of the 2011 Subpoena. (Ex. 8.) This request is also encompassed by Document Requests 1, 2, 5-8, 10, 15-18, 20, 27, 38, 45, 46 in the 2010 Subpoena. (Ex. 1.)

ARGUMENT

I. THE REQUESTED DOCUMENTS ARE RELEVANT

Parties “may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense.” Fed. R. Civ. P. 26(b)(1). Here, Ven-A-Care alleges that Defendants caused the federal government to overpay all fifty states for Medicaid drug reimbursements based on “false” AWP and WAC information provided by the Defendants. To prevail on these claims and recover damages, Ven-A-Care must show, *inter alia*, that Defendants’ AWP and WACs are “false” and that Defendants acted “knowingly,”¹⁴ and that Defendants’ alleged misrepresentations were material and caused the government to overpay.¹⁵ Relevant to these issues is Florida’s method of reimbursing pharmacies for prescription drugs dispensed under Medicaid and any changes to the reimbursement formula over time; the rationale for adopting the reimbursement formula, including policy decisions made by CMS and the State in permitting reimbursements at certain levels and relying on certain pricing data; communications between CMS and AHCA regarding Medicaid drug reimbursements and their understanding of pricing terms like AWP, WAC, and AMP; and analyses and surveys of actual acquisition costs by Florida pharmacies to which CMS or AHCA had access.

Defendants seek discovery of facts that go precisely to these issues. The first category of documents that Sandoz requests – Medicaid State Plans and State Plan Amendments – is clearly relevant. These materials are the official policy documents of the Florida Medicaid program, approved by CMS, which set forth the methodology under which the State reimburses

¹⁴ See 31 U.S.C. § 3729(a).

¹⁵ See *United States ex rel. Sanders v. N. Am. Bus Indus.*, 546 F.3d 288, 297-299 (4th Cir. 2008) (dismissing False Claims Act claims where alleged misrepresentations were not material and where the alleged misrepresentation did not cause the government to pay out money or forfeit money due).

for drugs dispensed by pharmacies. These materials are the basic building blocks for understanding how the State reimburses for drugs under Medicaid and how its method of reimbursement has changed over time.

Likewise, the second category of requested documents is relevant. The custodians from whom Defendants request production are AHCA officials who are likely to possess information relevant to crucial issues in this case or information likely to lead to the discovery of relevant evidence. These officials currently or formerly worked in the following AHCA offices:

- **Office of the Deputy Secretary of Medicaid.** This office appears to have responsibility for high-level decisions regarding the State Medicaid program.¹⁶
- **Bureau of Medicaid Pharmacy Services.** This office is responsible for managing the Medicaid prescribed drug program, and it manages the manufacturer rebate program and the vendors that support the prescribed drug program.¹⁷ The requested documents include those of Jerry Wells, a former bureau chief who previously has testified in AWP-related litigation.

¹⁶ The document custodians from whom Defendants seek production are Sybil Richard, former Deputy Secretary of Medicaid; Robert Sharpe, former Assistant Deputy Secretary of Medicaid; and Gary Crayton, former Deputy Director Medicaid.

¹⁷ See AHCA Medicaid Services, <http://ahca.myflorida.com/Medicaid/about/about3.shtml> (last visited May 19, 2011). The document custodians from whom Defendants seek production are current and former Bureau Chiefs George Kitchens, Anne Wells, and Jerry Wells; Government Analysts Ray Aldridge and Marie Donnelly; former Pharmacists Linda Barnes, Stephen Lipscomb, Jane Mann, Susan McLeod, Jim Powers, and Sue Preacher; Staff Assistant Darlene Frost-Penn; and former employees Regina Wiggins and Jason Ottinger.

- **Bureau of Medicaid Program Analysis.** This office is responsible for fiscal and budget planning, data analysis and forecasting, and setting rates for certain providers.¹⁸

In addition, Defendants' requested searches of these custodians' files are targeted to elicit relevant documents. Defendants request documents containing key pricing terms ("AWP," "WAC," "AMP"), references to or communications with the federal government regarding drug reimbursements ("CMS," "State Plan," "SPA," "4.19B"), discussion of drug reimbursements ("Estimated Acquisition Cost," "pharmac! /5 reimb!", "reimbursement for drugs," "acqui! /5 cost," "nondiscounted /5 AWP," "unmodified AWP"), and analyses of pharmacy acquisition costs conducted by outside vendors ("Myers and Stauffer," "Abt," "Provider Synergies"). All these terms – to be run in an already narrowed database of custodians likely to have responsive documents – seek documents that are relevant to the claims and defenses in this action.

II. DEFENDANTS' REQUESTS ARE REASONABLE

Defendants' requests are reasonable, and the State has no basis to claim that they are overbroad, available from other sources, or unduly burdensome. *See* Fed. R. Civ. P. 26(b)(2)(C); 45(c)(3)(A)(iv); *see also Behrend v. Comcast Corp.*, 248 F.R.D. 84, 86 (D. Mass 2008) ("When determining whether a subpoena *duces tecum* results in an undue burden on a party such factors as the relevance of the documents sought, the necessity of the documents sought, the breadth of the request . . . expense and inconvenience can be considered.") (citation omitted) (internal quotation marks omitted).

¹⁸ *See id.* The document custodians from whom Defendants seek production are Greg Bracko, Medicaid Healthcare Program Analyst, and Ralph Quinn, Senior Database Analyst.

As an initial matter and as discussed above, the requested documents are highly probative of the claims and defenses in this case. Their relevance outweighs any claim of burden by the State.

Moreover, Defendants' requests are narrowly drawn and seek documents not available elsewhere. Defendants have significantly scaled back the categories of documents requested for production since serving the Subpoena in June 2010.¹⁹ Defendants seek a narrow subset of Florida Medicaid documents: Florida's Medicaid State Plans regarding pharmaceutical reimbursement, and documents from the files of AHCA employees who were pre-selected by the State and are the people most likely to have responsive information. With regard to the latter, Defendants' proposed search terms reduce the number of documents to be produced by about 79%, from about 719,000 to 153,000 documents. Defendants have also undertaken significant efforts to obtain responsive documents through other means, by reviewing and evaluating the Mylan and CMS productions before asking the State to produce documents.

Any assertion of undue burden by the State is without merit. The State, in fact, would incur no real burden, as it likely would have to produce the same documents requested here in the related state action, in which Florida is a plaintiff. That case and this federal case overlap significantly. Both lawsuits were brought by the same relator, Ven-A-Care, which is represented by the same counsel.²⁰ Both cases share Sandoz and Actavis as defendants.²¹ The same underlying conduct is at issue in both cases – *i.e.*, the alleged reporting by drug manufacturers of “false” AWP and WACs that caused the government to overpay for Medicaid

¹⁹ Compare 2010 Subpoena (Ex. 1), with 2011 Subpoena (Ex. 8).

²⁰ Second Amended Complaint, *State of Florida ex rel. Ven-A-Care of the Florida Keys, Inc. v. AlphaPharma, Inc., et al.*, Civil Action Nos. 98-CA-3032F, 03-CA1165A (Ex. 5).

²¹ *Id.*

reimbursements.²² Both cases involve alleged violations of false claims acts, the Florida False Claims Act and the federal False Claims Act.²³ The cases do differ in that Florida's production in the state case is likely to be far more extensive than in federal case. Defendants here have scaled back their requests and do not seek such discovery as to missing claims data or the files of custodians that the State excluded from its electronic database.²⁴ To the extent Florida produces documents in the federal action, it likely would have to do so anyway in the state action. Accordingly, the State has no basis to assert the requests here are unduly burdensome. *See Plant Genetic Sys., N.V. v. Northrup King Co., Inc.*, 6 F. Supp. 2d 859, 862 (E.D. Mo. 1998) (in denying nonparty's motion to quash subpoena in a patent infringement lawsuit, the court found no undue burden where the movant was a party to other lawsuits involving the disputed technology and "it would seem likely the requested witness and documents have already been or will have to be produced elsewhere.").

²² *Id.* ¶¶ 28-29, 33-36.

²³ *Id.* ¶¶ 1-2, 46-60.

²⁴ For example, despite the apparent relevance, Defendants have not asked the State to produce documents kept by officials in the Bureau of Medicaid Contract Management (which manages the contract for the Medicaid fiscal agent and interfaces with Medicaid providers) or the Bureau of Medicaid Services (which is responsible for the development, coordination, and implementation of Medicaid program policies and procedures; prepares budget justifications for program issues; and analyzes the impact of new and amended state and federal laws and rules). *See* AHCA Medicaid Services, <http://ahca.myflorida.com/Medicaid/about/about3.shtml> (last visited May 19, 2011).

III. THIS COURT HAS AUTHORITY TO HEAR DEFENDANTS' MOTION TO COMPEL

This Court has authority to enforce the subpoenas, which issued from the United States District Court for the Northern District of Florida. The Court's authority derives from the statute governing multidistrict litigations:

Such coordinated or consolidated pretrial proceedings shall be conducted by a judge or judges to whom such actions are assigned by the judicial panel on multidistrict litigation. . . . The judge or judges to whom such actions are assigned . . . *may exercise the powers of a district judge in any district* for the purpose of conducting pretrial depositions in such coordinated or consolidated pretrial proceedings.

28 U.S.C. § 1407(b) (emphasis added); *see also In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 245 F.R.D. 55, 57 (D. Mass 2007) ("The relevant statutes and caselaw provide for an MDL Court to resolve disputes arising from the service of Rule 45 subpoenas on non-parties located in other districts"); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 444 F.3d 462, 468-69 (6th Cir. 2006) ("A judge presiding over an MDL case therefore can compel production by an extra-district nonparty; enforce, modify, or quash a subpoena directed to an extra-district nonparty; and hold an extra-district nonparty deponent in contempt, notwithstanding the nonparty's physical situs in a foreign district where discovery is being conducted."). The MDL court's authority extends to document-only subpoenas such as the one at issue here. *See In re Neurontin Mktg. Litig.*, 245 F.R.D. at 57; *Pogue*, 444 F.3d at 469 n.4 ("the rationale underlying the MDL statute of 'just and efficient' resolution of pretrial proceedings requires the conclusion that Section 1407(b)'s grant of authority applies to both deposition subpoenas and documents-only subpoenas").

CONCLUSION

For the reasons set forth above, the Court should issue an order granting (1) Defendants' motion and compelling AHCA to produce the requested documents; and (2) such other and further relief as may be proper and just.

Dated: May 20, 2011

Respectfully submitted on behalf of all Defendants

By: /s/ Heather K. McDevitt
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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing (1) DEFENDANTS' MOTION TO COMPEL THE STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION TO PRODUCE DOCUMENTS; (2) DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO COMPEL THE STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION TO PRODUCE DOCUMENTS; and (3) PROPOSED ORDER were delivered to all counsel of record and to counsel of the United States by electronic service in accordance with Paragraph 11 of the Case Management Order No. 2, by sending on May 20, 2011, a copy to Lexis-Nexis for posting and notification to all parties. I further certify that I have caused a true copy of the same to be delivered to counsel for non-party Florida Agency for Health Care Administration via electronic mail and UPS.

/s/ Daniel Cohen

Daniel Cohen